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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,687	RAULT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 - 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 - 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed July 24, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 24, 2009 has been entered.

Claim Rejections - 35 USC § 112 – 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17 – 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation "only one pharmaceutically active substance, which is diclofenac or a pharmaceutically acceptable salt thereof". This limitation excludes the presence of other pharmaceutical active ingredients from the film coated tablet. The exclusion of other pharmaceutically active ingredients does not appear in the specification filed and introduces a new concept that was not present in the originally filed disclosure.

If Applicant is in disagreement with the Examiner regarding support for the amended claim, Applicant is respectfully requested to point to page and line number wherein support may be found for the instant invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 17 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al. (US 6,558,701) in view of De Haan et al. (US 2006/0051420) and SEPIFILM® product page (accessed 4/10/09). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed April 24, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Bartholomaeus et al. teaches a multilayer tablet (minimum of 3) tablet with two active ingredients with an internal separation layer, that the Examiner has equated with a coating, but these two parts are distinct. With only one moiety, separating layer is a meaningless term and also mentions coating as a distinct, optional element of the composition. The argument for optimization of parameters is traversed and the Examiner is asked to identify where the

reference teaches deletion of one active ingredient, the separation layer composition be applied as a coating, that the coatings are not optional and recited the guidance given that leads the practitioner to the 'desired result'. In regards to De Haan and the SEPIFILM product page, Applicants argue that the non-preferred genus of film contains a large number of film materials and it is not taught that the film with have the desired stabilizing effect. Therefore it would not be obvious without undue experimentation to choose a film from a genus of less desirable films and one would more likely select a sugar or sugar film coating. Thus, De Haan et al. teaches away from the coating of the present invention and the SEPIFILM reference teaches that certain films are known in the art, as is known from the specification.

These arguments are unpersuasive. Many of the elements which Applicant request a citation as to where Bartholomaeus et al. teaches them, e.g., removal of the second active ingredient, are not required by the instant claims. The various elements of the film coated tablet are introduced using the transitional phrase "consisting essentially of". The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ

409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). **For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."** See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) **MPEP 2111.03** The specification of the instant application discloses tablets that contain diclofenac compositions that useful for administration to patients. This is the same activity described by Bartholomaeus et al. for its compositions. The addition of tramadol in a separate core of the tablet to this composition provides a second analgesic ingredient upon administration of the tablet to a patient, but does not change or "materially affect" the administration of the tablet dosage form to a patient. Thus, the tramadol present in an additional core in the tablet is not excluded from the instant claims. An outer coating can also be a separating layer as it separates the core from the external environment. The instant claims do not require the coating to the outermost layer of the tablet and as other layers may be present, the separating layer of Bartholomaeus et al. can read on the film coating of the instant

claims. As a second core can be present in the composition, "separation layer" is not a meaningless term. Bartholomaeus et al. teaching that coatings are optional means that two different embodiments with respect to a coating are envisioned, one without a coating but with the separating layer, and one with a coating and a separating layer, nd in the latter embodiment, a coating is not optional.

The motivation need not be found in the cited references themselves (see MPEP 2141 for more information) but can be found in the knowledge of one of ordinary skill in the art. While parameters such as tablet hardness or compressibility are not explicitly recited by the instant claims or Bartholomaeus et al., such parameters are known to one of ordinary skill in the art to be important properties for a tablet that will need be optimized. Altering the amounts of binders or other excipients present will alter these properties and others. In order to overcome a prima facie case of obviousness, it is incumbent upon the Applicant to provide comparative test evidence that demonstrates unexpected superiority of the claimed compositions versus the closest prior art compositions, and not simply an advantage predictable from the prior art. See *In re Chapman*, 148 USPQ 711, 715 (CCPA, 1966). Moreover, such proffered comparisons must be commensurate in scope with the breadth of the claims. See *In re Clemens*, 206 USPQ 289, 296 (CCPA, 1980) and *In re Coleman*, 205 USPQ 1172, 1175 (CCPA 1980). The examples in the specification to not make such a comparison and are not commensurate in scope with the claims are therefore insufficient to overcome the prime facie case of obviousness.

Similarly, it also would be obvious to one of ordinary skill in the art to optimize the dosage of the active ingredient as the dosage of active ingredient is a results effective parameter. Based on the severity of the condition, the physical condition of the patient (age, weight, other medical conditions or medications, etc.) and the dosing schedule for the tablet, the amount of active ingredient would be optimized to provide a dosage form with a therapeutically effective amount of the drug with minimal side effects.

De Haan et al. stating that certain films are less desirable than sugar or sugar films does not rise to the level of teaching way. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). (MPEP 2123). Furthermore, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). **MPEP 2123**, emphasis added. Relevant for rejections under 35 USC 103 is whether one of ordinary skill would have a reasonable expectation of success in coating the formulations with the various coatings. There is nothing in De Haan et al. or SEPIFILM product page to suggest that such coatings could be applied to tablets for increased stability. The discovery of the beneficial effects of particular films on the stabilization of the active ingredient is also not relevant to patentability. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the

discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). The SEPIFILM® LP product page clearly states that such coatings improve the stability of moisture sensitive or hygroscopic formulations (p 1).

8. Claims 17 – 19 and 21 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al., De Haan et al. and SEPIFILM® product page as applied to claims 17 – 19 and 21 – 23 above further in view of Gimet et al. (US 5,601,843).

Bartholomaeus et al. discloses a tablet dosage with a core containing diclofenac sodium or potassium, excipients such as MCC, HPMC, silicon dioxide and stearic acid. This dosage form also contains a layer comprised of HPMC, MCC, stearic acid and titanium dioxide.

Bartholomaeus et al. dose not explicitly describe a dosage containing from 2 – 15% by weight MCC in the tablet core.

Gimet et al. discloses pharmaceutical compositions comprising a core of either diclofenac or piroxicam and a mantle with a prostaglandin (figure 1, col 1, ln 65 – col 2, ln 1). In example 1, a core with 50 mg diclofenac sodium and about 15% by weight of the core MCC is prepared.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare a tablet core containing diclofenac and amount of MCC around 15% (w/w). The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Gimet

et al. discloses that tablet cores with diclofenac can be prepared with lesser amounts of MCC and excipients such as lactose monohydrate, corn starch and povidone than that used in Bartholomaeus et al. The selection of excipients and the amount of those ingredients is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Depending on the availability, interactions of the excipients with each other and the active ingredient asn the desired physical properties of tablet core (hardness, compressibility, flowability of the raw materials, disintergration and release profile, etc.), one of ordinary skill would optimize the excipients and amounts of those excipients present in the tablet core and coating.

9. Claims 17 – 19 and 21 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al., De Haan et al. and SEPIFILM® product page as applied to claims 17 – 19 and 21 – 23 above further in view of Humbert-Droz et al. (US 6,083,531).

Bartholomaeus et al. discloses a tablet dosage with a core containing diclofenac sodium or potassium, excipients such as MCC, HPMC, silicon dioxide and stearic acid. This dosage form also contains a layer comprised of HPMC, MCC, stearic acid and titanium dioxide.

Bartholomaeus et al. dose not explicitly describe a dosage containing 12.5 mg of diclofenac potassium as the active ingredient.

Humbert-Droz et al. discloses fast melt oral dosage form that contain 12.5 mg of diclofenac potassium per unit (examples 1 – 5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a multilayer tablet dosage from as taught by Bartholomaeus et al. containing 12.5 mg of diclofenac potassium, taught by Humbert-Droz et al. as an useful dosage of diclofenac when orally administered. The dosage of an active ingredindets is a results effective parameter that a person of ordinary skill in the art would routinely optimize. An optimal dose is smallest dosage of active ingredient that provides the desired therapeutic effect will minimize side effects arising from higher doses.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gimet et al. (US 5,601,843) in view of Humbert-Droz et al. (US 6083531), Voss et al. (US 4,690,927), De Haan et al. (US 2006/0051420), and the SEPIFILM® product page (accessed 4/10/09).

Gimet et al. discloses pharmaceutical compositions comprising a core of either diclofenac or piroxicam and a mantle with a prostaglandin (figure 1, col 1, ln 65 – col 2, ln 1). In example 1(col 7), a core with 50 mg diclofenac sodium, 4.8 mg povidone, 12.9 mg MCC, 13.0 mg lactose monohydrate and 8.4 mg corn starch (maize starch) is

prepared. A mantle, which reads on a coating, containing misoprostol, a prostaglandin, HPMC and microcrystalline cellulose is applied.

Gimet et al. does not disclose the potassium salt of diclofenac, the presence of silica colloidal anhydrous or sodium starch glycolate in the tablet core or the inclusion of stearic acid or microcrystalline cellulose in the coating and does not explicitly disclose a 12.5 mg dosage.

Humbert-Droz et al. discloses fast melt oral dosage form that contain 12.5 mg of diclofenac potassium per unit (examples 1 – 5).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the potassium salt version of diclofenac in the composition of Gimet et al. with a dosing of 12.5 mg per tablet. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Humbert-Droz et al. discloses that dosage forms with a 12.5 mg dosage of potassium salt can be prepared and given orally to produce the desired therapeutic effect.

Voss et al. discloses a tablet comprising diclofenac sodium, corn starch, colloidal silica, sodium carboxymethyl starch (PRIMOJEL®; sodium starch glycolate) and magnesium stearate to form a granulate that is tableted (col 3, ln 10 - 23). A coating to mask the bitter taste of diclofenac, protect the diclofenac from light and make for easier swallowing of HPMC and titanium dioxide was applied. These dosage forms disintegrate and release the active ingredients rapidly when exposed to water or physiological media.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate excipients such as sodium starch glycolate into the tablet core. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Voss et al. discloses that such core compositions with enteric coatings dissolve rapidly when exposed to water and provide easy to swallow dosage forms with no bitter taste and the white titanium dioxide protects diclofenac from light.

De Haan et al. discloses a stabilized pharmaceutical dosage form provided with a coating (abstract). One film coating applied to the tablets is SEPIFILM® LP770, which consists of HPMC, stearic acid and talc (¶ [0052]). The SEPIFILM® LP770 product page indicates that a white version of the coating is also available, in contrast to the clear version of the product, but both products decrease water vapor transmission rates (p 1 – top of 2). The instant specification (¶ [0018] of the PGPub) indicates that SEPIFILM® LP 770 White contains 60 – 70% HPMC, 8 – 12% stearic acid, 5 – 15% microcrystalline cellulose (MCC) and 10 – 20% titanium dioxide.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to coat the tablets with a coating such as SEPIFILM® LP770, which contains HPMC, stearic acid, MCC and titanium dioxide. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because the diclofenac dosage forms with excipients such as starch, silica, sodium starch glycolate and magnesium stearate disintegrate quickly when exposed to water. In addition to the benefits disclosed by Voss et al. for the

coating, the SEPIFILM® coating would also decreases water vapor transmission, which could lead to exposure of the cores to water during manufacture or storage. That exposure could result in disintegration of the tablet prior to use by exposing the core to water.

Claim 24 uses a variety of transitional phrase. Because of the "consisting of" language used in the preamble, the tablet itself must consist of a core and a single coating layer. However, the ingredients contained within each of those elements is open as the list of ingredients in each elements uses the transitional phrase of "consisting essentially of" and "comprising" respectively. As discussed is greater detail above, "consisting essentially of" is being interpreted as equivalent to comprising. Therefore formulations with more than one pharmaceutically active ingredient are not excluded by the instant claims. Even if the claims were limited to a single pharmaceutically active ingredient, Humbert-Droz et al. discloses that dosage forms with diclofenac as the only pharmaceutically active ingredient can be prepared. While the prostaglandin of the dosage form of Gimet et al. can prevent NSAID induced ulcers (col 1, ln 38 – 40 of Gimet et al.), prostaglandins also inhibit platelet aggregation, cause bronchodilation and act to induce labor and abortion in the first trimester of pregnancy (col 6, ln 20 – 38 of US 6013823). Such side effects would motivate one of ordinary skill to produce a dosage form without prostaglandins, while not preventing NSAID induced ulcers in patients, would also not cause the abortion or decrease the ability of the blood to clot.

The selection of excipients and the amount of those ingredients is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize.

Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Depending on the availability, interactions of the excipients with each other and the active ingredient and the desired physical properties of tablet core (hardness, compressibility, flowability of the raw materials, disintegration and release profile, etc.), one of ordinary skill would optimize the excipients and amounts of those excipients present in the tablet core and coating. Note, in order to overcome a prima facie case of obviousness, it is incumbent upon the Applicant to provide comparative test evidence that demonstrates unexpected superiority of the claimed compositions versus the closest prior art compositions, and not simply an advantage predictable from the prior art. See *In re Chapman*, 148 USPQ 711, 715 (CCPA, 1966). Moreover, such proffered comparisons must be commensurate in scope with the breadth of the claims. See *In re Clemens*, 206 USPQ 289, 296 (CCPA, 1980) and *In re Coleman*, 205 USPQ 1172, 1175 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW